FINEARTS-HF
FINerenone trial to investigate Efficacy and sAfety superioR to placebo in paTientS with Heart Failure

Scientific Sessions

Efficacy Of Finerenone In Patients With Heart Failure And Mildly Reduced Or Preserved Ejection Fraction: A Pre-specified Analysis Of Heart Rate In The Finearts-hf Trial

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#AHA25

DISCLOSURES

I have received research grants from the Daiwa Foundation and the Japan Research Foundation for Clinical Pharmacology.

The FINEARTS-HF trial was sponsored by Bayer AG.

BACKGROUND: HEART RATE IN FINEARTS-HF

- **Resting heart rate (HR) is a prognostic factor in HFrEF, where higher HR correlates with higher risk and HR-lowering improves outcomes[1]. These findings appear to apply only to sinus rhythm (SR) and not atrial fibrillation (AF)[2]. However, it is unclear whether similar associations between HR and outcomes exist in HFmrEF or HFpEF and how heart rhythm influences them[3].**

- **The influence of MRAs on HR has not been reported, although a reduction in HR is hypothetically possible given reports that aldosterone modulates catecholamine release[4].**

- **The consistency of the therapeutic benefits of MRAs across the range of HR (and according to heart rhythm) has not been characterized in patients with HFmrEF/HFpEF.**

[1]Lancet. 2010;376:886-894; [2]Lancet. 2014;384:2235-2243; [3]Eur J Heart Fail. 2015;17:1182-1191; [4]Pharmacol Rev.1972;24:411-426

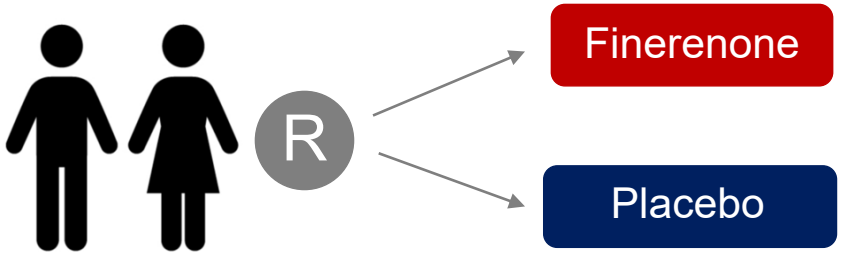
OBJECTIVE: HEART RATE IN FINEARTS-HF

The aim of this study was to examine the association between baseline HR and clinical outcomes according to heart rhythm, and to evaluate the effect of finerenone across the HR spectrum in patients with HFmrEF/HFpEF.

TRIAL DESIGN: HEART RATE IN FINEARTS-HF

Key Inclusion Criteria

- LVEF ≥ 40%
- NYHA functional class II-IV
- Elevated natriuretic peptide levels
- Structural heart disease (LA Enlargement or LVH)
- Hospitalized, recently hospitalized, or ambulatory
- Diuretics in the 30 day prior to randomization



Primary endpoint

Total (first and recurrent) HF events (unplanned HF hospitalizations or urgent HF visits) and CV death

Assessment of Heart Rhythm and Data Exclusion Criteria

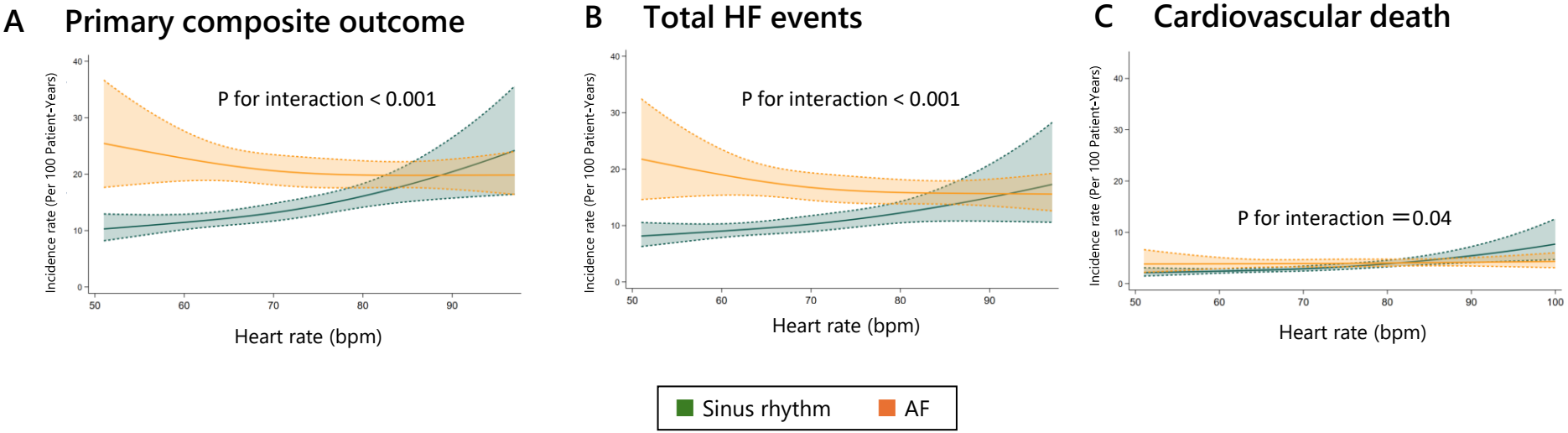
Underlying rhythm (sinus or AF) was determined from the baseline ECG.

Patients with pacemaker rhythm, missing ECG data, or missing HR records were excluded.

Baseline characteristics: HEART RATE IN FINEARTS-HF

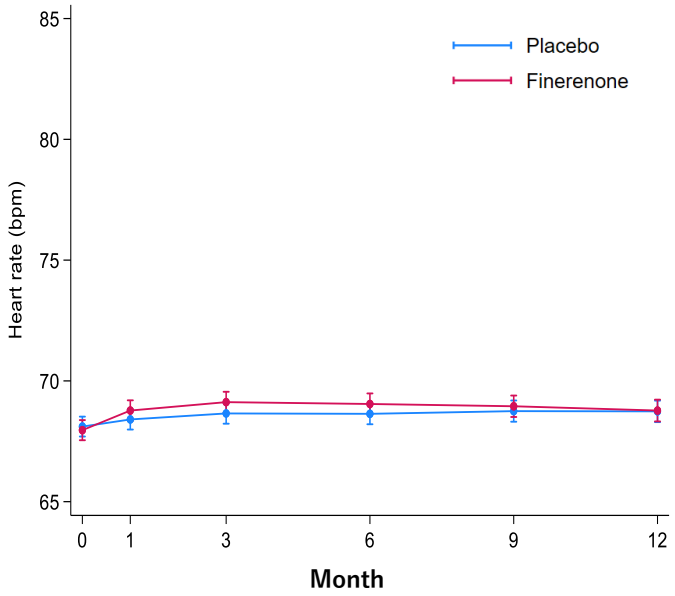
	Sinus Rhythm			Atrial Fibrillation		
	HR, ≤63 bpm (n = 1197)	HR, 63-72 bpm (n = 1188)	HR, >72 bpm (n = 1112)	HR, <71 bpm (n = 735)	HR, 71-83 bpm (n = 750)	HR, ≥83 bpm (n = 705)
Age (years)	72 ± 9	70 ± 10	69 ± 11	75 ± 9	75 ± 9	73 ± 9
Female – (%)	45	48	44	41	46	53
NYHA functional class Ⅲ or Ⅳ – (%)	24	27	32	32	35	41
LVEF (%)	53 ± 8	53 ± 8	52 ± 8	53 ± 8	53 ± 7	52 ± 8
NT-proBNP (pg/mL)	552 (337-1094)	576 (288-1234)	580 (290-1406)	1713 (1163-2771)	1682 (1130-2579)	1802 (1135-2898)
eGFR (ml/min/1.73m^2)	62 (48-78)	65 (49-82)	66 (49-82)	58 (45-71)	57 (45-72)	58 (46-74)
Potassium (mmol/L)	4.4±0.5	4.4±0.5	4.4±0.5	4.3±0.5	4.3±0.5	4.4±0.5
Beta-blocker – (%)	84	86	79	83	90	90
Digoxin – (%)	2	1	2	17	19	19
Amiodarone – (%)	13	8	6	7	5	6

CLINICAL OUTCOME: HEART RATE IN FINEARTS-HF



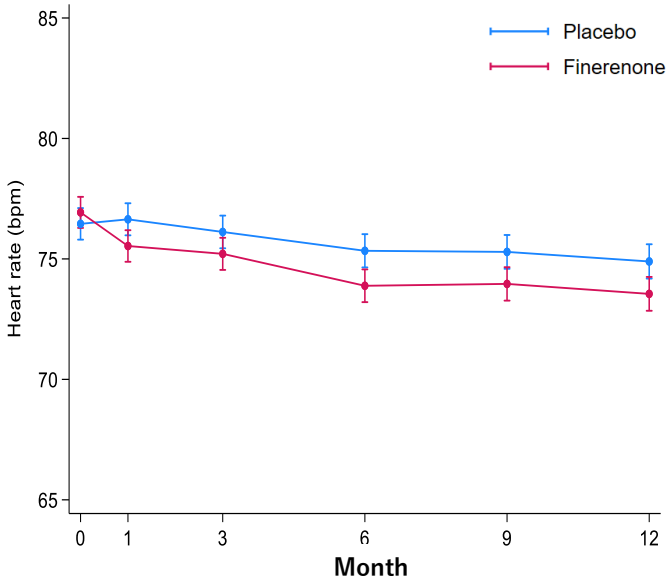
CHANGE IN HEART RATE : HEART RATE IN FINEARTS-HF

Sinus rhythm



The mean placebo-corrected difference from randomization to 12 months
0.03 (-0.57 to 0.64) bpm p=0.91

Atrial fibrillation

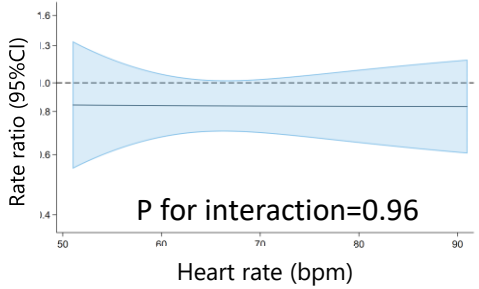


The mean placebo-corrected difference from randomization to 12 months
-1.35 (-2.29 to -0.41) bpm p=0.005

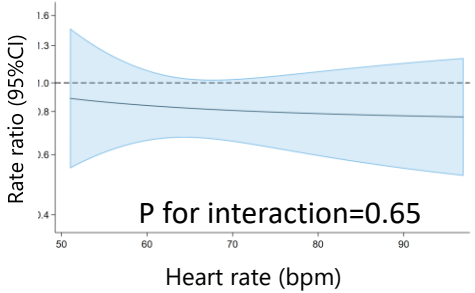
TREATMENT EFFECT: HEART RATE IN FINEARTS-HF

Sinus rhythm

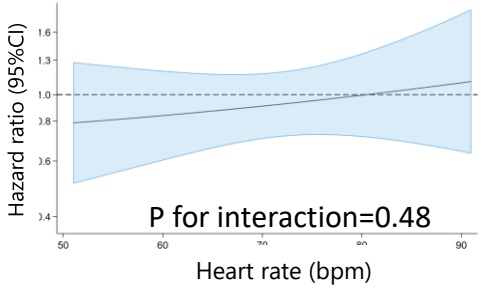
A Primary composite outcome



B Total HF events

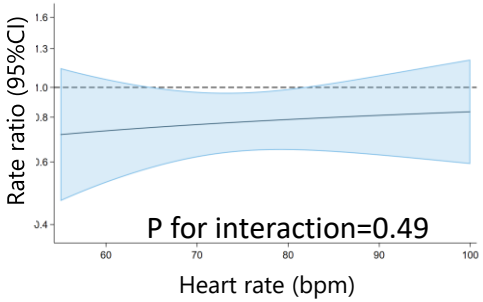


C Cardiovascular death

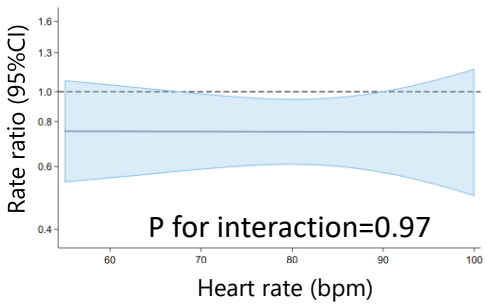


Atrial fibrillation

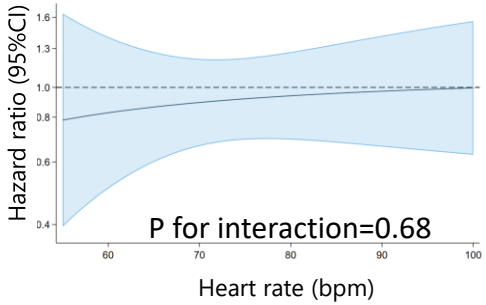
A Primary composite outcome



B Total HF events



C Cardiovascular death



SUMMARY AND CONCLUSIONS: HEART RATE IN FINEARTS-HF

- **In patients with HFpEF/HFmrEF in the FINEARTS-HF trial, higher baseline HR was associated with a higher risk of clinical outcomes among patients in SR, but not in those in AF.**
- **Among patients in SR, there was no significant difference between finerenone and placebo in change in HR from baseline to 12 months. In contrast, among patients with AF, finerenone modestly reduced HR from baseline to 12 months compared with placebo.**
- **The effect of finerenone on the primary outcome and its components was consistent across the HR spectrum, irrespective of rhythm.**

This paper is *in press* in the *European Journal of Heart Failure.*